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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,711	03/23/2004	Nita Mody	36554US1	2665
116	7590	11/23/2005	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/806,711

Applicant(s)

MODY, NITA

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,43 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,43 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 08/18/05 is acknowledged and entered. Claims 1-34, 36-42 and 44-45 are cancelled. Claims 35, 43 and 46-50 are pending in the application. The examiner believes that the Applicant's indication that claims 44 and 45 are pending as original claims is an error.

Response to Amendment

2. Finality of the last Office action is withdrawn and a new ground of rejections is established. Objection to the specification remains the same.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing "a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same ... in its best mode".

It seems that the disclosure is an attempt to cover all possible embodiments involving pH indicators incorporated into single- or multi-layered matrices comprising a variety of materials from non-permeable to superabsorbent, with most of the embodiments well known in the art. Some of the embodiments, e.g. those involving "fluid barrier layers", which are not permeable to the fluid to be detected, are not enabled, since no fluid can be detected in such layers or can get through these layers to reach another layer with the incorporated pH indicator. The variety of the embodiments covering all possible materials used for detecting or controlling biological fluids or moisture by employing pH indicators disclosed in the specification does not allow to clearly and unambiguously identify the essence of the invention and its distinction from the prior art.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35, 43 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites a first ink layer and a second ink layer, wherein “at least one of said layers” comprises a pH-indicating agent. If there is just one layer comprising the pH-indicating agent, then it is not clear as to why the second layer is called the “ink layer”, and if it comprises any ink. Moreover, it is not clear, as to what the second ink layer comprises, since the claim does not recite any components of the second composite layer, which renders claim 35 unclear and indefinite. Since the second ink layer is not defined in any dependent claims, they are all rendered unclear and indefinite.

Claim 35 further lists such different fluid regulating materials, as silica gel (particles), clays (“a fine-grained, firm earthy material that is plastic when wet and hardens when heated, consisting primarily of hydrated silicates of aluminum and widely used in making bricks, tiles, and pottery”, according to Dictionary.com, and which is used in a cat litter because of its properties), supeabsorbent polymers (fibers), etc.; it is unapparent to the examiner as to how all these different materials of diverse nature and properties can be “dispersed through the thickness of said matrix”? How the polymer can be dispersed through the polymer? In claim 43 the indicator of claim 35 is recited to be a part of an absorbent article worn on a user’s body. It is not clear, how the indicator comprising clay, which hardens upon drying, can be a part of the article worn on the user’s body?

Claim 46 is completely unclear. If pH indicator is dry, how can it bleed into the fluid?

Claim 47 is unclear. The properties of the wetness indicating ink comprising a polymer, a pH indicating agent and “a fluid regulating additive in an amount effective to provide a cured or dried layer of said ink ... with sufficient moisture transmission” are not apparent to the examiner. The examiner would assume that these are primarily the properties of the polymer,

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which determine the moisture transmission through the ink layer. It is not clear, how the fluid regulating additive can affect transmission of the fluid if the polymer is e.g. a highly hygroscopic polymer?

In claim 48 it is not clear, what the term “a solvent ink” might be? Is this a solvent containing the ink? Is this a dye, which is also a solvent? The term “solvent ink” is unclear and indefinite. Moreover, it is unclear as to what “solvent soluble or solvent dispersible fluid regulating additive” might be. Solubility or “dispersibility” of the additive depends on the solvent used, and therefore the expression renders the claim unclear and indefinite, as it is not clear, which solvent is recited in the claim.

In claim 49 it is not clear, what is specifically “radiation curable” in the ink, since the ink of the parent claim is a composite material comprising the polymer, the pH-indicator and the fluid regulating additive. Should all the components be “radiation curable”? The language of the claim is so indefinite that it prevents the examiner from searching the prior art for the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 35, 43 and 46** are rejected under 35 U.S.C. 102(b) as being anticipated by Allan et al. (US 2001/0037101 A1).

Allan discloses a wetness indicator “comprising at least two segregated or intermixed superabsorbent polymers [SAPs], wherein each superabsorbent polymer, or one less than each superabsorbent polymer, is incorporated throughout with a latent indicator peculiar to that superabsorbent polymer so that each superabsorbent can be distinguished from each other upon development of the indicators” (page 1 [0006]). The wetness indicator can be a part of a diaper (page 1, [0015]). “Examples of suitable latent indicators include ...pH sensitive indicators (acid or base)” (page 1 [0014]). SAPs can be of high permeability and slow absorption, or of low

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permeability and high absorption, so that they regulate the flow of the fluid (page 1 [0003]).

The combination of several portions of SAPs, part of which are intermixed and part are segregated provides at least two ink layers recited in the claims.

8. **Claims 47-48 and 50** are rejected under 35 U.S.C. 102(b) as being anticipated by JP 60178362A2 or JP 05034334A (Abstracts) as evidenced by Deffeyes (US 4,036,360).

The indicated prior art discloses a wetness indicating ink comprising a polymer, a pH indicating agent and a fluid regulating additive with the additive dispersed in the ink layer sufficient for the fluid to be transmitted to the pH indicator. Fluid regulating additive is a water absorbing powder. While the examiner does not have translation of JP applications at this time and the abstracts do not specify water absorbing powder, Deffeyes indicates “among the dessicants which can be used are alumina, bauxite, anhydrous calcium sulfate, water-absorbing clays, silica gel, zeolite and any of the other moisture-absorbing materials known to the art” (col. 2, lines 23-31), which makes it obvious that the Japanese applications disclose at least some of the materials recited in claim 50, since they are conventional water-absorbing additives. Deffeyes is used only as an evidence for defining water-absorbing materials conventional in the art, not as a secondary reference.

Response to Arguments

9. Applicant's arguments filed on 08/18/05 have been considered but are moot in view of the new ground(s) of rejection.

The examiner only would like to comment on the arguments regarding the specification. First paragraph of 35 U.S.C. 112 explicitly recites: “the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention”. While the Applicant admits that the “specification is broadly drafted”, he assumes that “the one skilled in the art is enabled to make and use the invention”. The examiner's position is that the specification is so broadly drafted, that it is very difficult to understand, what it discloses as an invention. As it was

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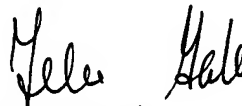
indicated in the previous Office action, "the specification discloses all possible embodiments of single- and multi-layer wetness indicators comprising layers with pH indicators and "fluid regulating additives", with the additives from the list comprising all possible absorbents, from impermeable to superabsorbent". The specification does not meet the requirements of 35 U.S.C. 112, first paragraph, and is considered unacceptable by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/17/05


YELENA GAKH
PRIMARY EXAMINER